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08/696,997	11/04/96	ANDERSON S	FREBR2173P00

QM41/0408
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EXAMINER	
HUANG, S	
ART UNIT	PAPER NUMBER
3736	9

DATE MAILED:
04/08/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/696,987	Applicant(s) Anderson
	Examiner Stephen Huang	Group Art Unit 3311

☒ Responsive to communication(s) filed on *Dec 15, 1997* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133).. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, there is no antecedent basis for "the amount of forced expiratory volume".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1-21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lloyd et al. (US 5,660,166)

Lloyd et al discloses a system for the intrapulmonary delivery of aerosolized aqueous formulations. The system and method of Lloyd et al includes the inhaling of an effective amount of substance capable of altering the osmolarity of airway surface liquid. The substance is in the form of a dry powder and the system measures the subjects resistance to airflow in terms of FEV. (See column 11, lines 6-44) In column 4, Lloyd et al discloses the use of dry powder compounds to be inhaled by the patient. Lloyd further discloses in column 4, lines 15-24 and column 12,

lines 15-50, the packaging of the compound in a rupturable hard capsule. The compound that is delivered include salts, sugars and sugar alcohols. (See column 10, lines 14-48). Lloyd et al also discloses the size of the particles to be less than 7 microns (see column 6, line 44).

4. Claims 1-9 and 12-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Andersson et al..

Andersson et al discloses a system for dispensing pharmaceutically active compounds which has the patient inhale into their airways an effective amount of substance capable of altering the osmolarity of airway surface liquid in the form of a dry powder containing an effective proportion of particles of respirable size and measuring a parameter in a subject indicative of resistance to air flow in the subject's airways. In the abstract, Andersson et al discloses the method "for dispensing a clinically effective dose of inhalable, pharmaceutically active compound. The method includes providing a dry powder inhaler containing a powder including the pharmaceutically active compound, and administering to a patient a dose of the compound that is less than 70% of the dose that would be necessary to obtain a physiologically equivalent result were the compound administered by a pressurized metered dose inhaler. The pharmaceutically active compound is in the form of primary particles at least 80% of which have a particle size of less than 10 microns, and the primary particles are provided as agglomerates which are deagglomerated during inhalation so that at least 40% of the dose administered is in the form of primary particles." In column 1, lines 12-33, Andersson et al discloses several active compounds which may treat the patient. This group includes mineral salts, sugars and sugar alcohols. Further

Andersson et al discloses in the figures and the description of the figures the measuring of FEV in 1 second. (See column 5, lines 33-53)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 10-11 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al in view of Lloyd et al. (US 5,660,166)

Andersson et al discloses the method of dry powder inhalation treatment but does not disclose the rupturable hard capsule packaging of the instant invention. Lloyd discloses a similar system and method which incorporates the use of rupturable hard capsule which contain the dry powder in column 4, lines 15-24. Since both methods are directed to the same treatment it would have been obvious to one skilled in the art to incorporate the packaging means of Lloyd et al with the system of Andersson et al in order to provide for an effective transporting and storing medium of medicaments when not in use and being dispensed.

Response to Arguments

7. Applicant's arguments filed 12/15/97 have been fully considered but they are not persuasive.

The applicant has argued that the rejection based on Lloyd (US 5,660,166) should be traversed because Lloyd discloses a system for intrapulmonary delivery of aerosolized aqueous formulations. That is to say, Lloyd discloses the use of dry powders dissolved in a liquid prior to aerosolization. The applicant argues that the instant invention utilizes dry powders which are not dissolved in liquid. The examiner contends that there is nothing in the claims which might suggest that the dry powders are to be administered without being dissolved in liquid. The claims recite causing the patient to inhale a dry powder to provoke airway narrowing and then measuring air flow. This does not exclude the inhalation of aerosolized dry powder dissolved in a liquid. In light of this argument, the examiner believes the rejection based on the Lloyd reference should continue to stand.

The applicant has also argued that the rejection based on the Andersson reference should be traversed. Applicant argues that the instant invention is a marked contrast from Andersson. The instant invention uses dry powder to narrow the airways, causing a fall in FEV, while Andersson uses powder to improve lung function, thereby increasing FEV. However, the claims of the instant invention recite inhaling dry powder to alter the osmolarity of airway surface liquid. The examiner contends that the dry powders disclosed in Andersson are known in the art to alter the osmolarity of airway surface liquids in the subject. The particles are disclosed of to be of appropriate size to have an effect on the osmolarity of airway surface liquid. Although the Andersson reference does not disclose the inhalation of dry powder to effectuate a narrowing of airways, it does disclose the use of dry powder inhalation to cause a clinical effective alteration in

the osmolarity of airway surface liquid. The results of the FEV charts may reveal an improvement lung function. However, the examiner contends that the claims of the instant application merely recite a method to introduce dry powder into the airways to alter the level of osmolarity of airway surface liquid.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cloutier, Baum et al., Rubsamen et al (US 5,558,085; 5,507,277), Lloyd et al (US 5,522,385; 5,509,404; 5,497,763; 5,44,646) all disclose the use of dry powder inhalation to alter the osmolarity of airway surface liquid and the measuring of FEV to determine the subjects resistance in airways to air flow.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Huang whose telephone number is (703) 308-3399. The examiner can normally be reached on Mondays through Fridays from 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Bahr, can be reached on (703) 308-1066. The fax phone number for this Group is (703) 308-3139.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**jennifer.bahr@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

SDH

September 3, 1997